Engaging with Patients in Trials

The Science
The Practice
Engaging with Patients in Trials

The Science
From research subjects

Knowledge Creation (Researchers)

Knowledge Use (Clinicians)
To research partners

Knowledge Co-Production
(Patients as researchers)

Knowledge Co-Utilization
(Patients as caregivers)
Engagement in what?

Policy
- Media information about health promotion and public policy
- Public agency conducts focus groups with patients to ask opinions
- Patients participate in decisions about how to allocate resources

Healthcare Services Design & Delivery
- Public reporting of performance indicators
- Surveys of patient experience
- Patients co-lead safety and quality improvement committees

Research
- Education material about research results
- Focus groups to advise research team on research priorities
- Patients as co-investigator on research team

Direct Care
- Patients receive information about a diagnosis
- Patients are consulted about side-effects of treatment
- Patients co-manage their health condition with professionals

Adapted from Carman K L et al. Health Aff 2013;32:223-231
An Emerging Science

Peer-review publications on patient engagement in research

Boote, 2012; Barello 2012
The research community remains divided

ADVOCATES
- More Relevant Research
- Better Use in Practice
- Improved Patient-Oriented Outcomes

AGNOSTICS
WHERE IS THE EVIDENCE?

ATHEISTS
- Biased Research
- Conflicts of Interests
- Patients not representatives

Snape 2014; Becker 2010
Engagement
at what stage?

UPSTREAM
Doing the right research...

Priority-setting
Question
Governance

DOWNSTREAM
The research right...

Recruitment
Implementation
Knowledge translation

Picture from aktiasolutions.com
Potential benefits of patient engagement in research

• **Doing the right research…**
  
  • Alignment of research priorities with patients’ needs
  
  • Include *relevant outcome* (eg. fatigue, sleep, social isolation)

• **Doing the research right…**
  
  • Increased *recruitment rates*
  
  • More *logistically & culturally appropriate research*
  
  • Increased *sustainability of projects* beyond research project funding

Jagosh 2012
Patient engagement in priority-setting

A cluster randomized trial
(2007-2012)

Preparation (2007-2009)
- Engagement Intervention Review
  - 71 studies
  - 56 experts
  - 14 countries

Pilot (2010)
- Quality Indicators’ Review
  - 1489 quality indicators identified
  - 37 quality indicators included
- Engagement Intervention Pilot
  - Pilot site (n=1)
  - Patients (n=15)
  - Professionals (n=12)

Exploratory research site study
- Implementation evaluation (n=6 sites)

Patient Preparation & Baseline Consultation
- Study Sites (n=6)
  - Patients (n=83)

Trial (2010-2011)
- Intervention (Priority-Setting with Patient Engagement)
  - Study sites (n=3)
  - Patients (n=17)
  - Professionals (n=44)
  - Feedback on patient and professional consultation
  - Face-to-face deliberation with patients and professionals

Control (Priority-Setting Without Patient Engagement)
- Study sites (n=3)
  - Professionals (n=45)
  - Feedback on professional consultation
  - Face-to-face deliberation with professionals alone

Outcomes
- 1. Improvement Priorities
- 2. Intention to Implement
- 3. Prioritization Costs

Follow-up (2011-2012)
- Feedback and Implementation Support
  - Communication of group decisions to all participants
  - Implementation of group decisions in financial accountability contract

Boivin et al. The Milbank Quarterly, Vol. 92, No. 2, 2014 (pp. 319-350)
Boivin et al. Implementation Science 2011, 6:45
Patients and professionals have different priorities

- Access
- Respect & Empathy
- Treatment Cost
- Consultation Time
- Interprofessional Team
- Emergency Room Visits
- Technical Quality of Care

Patients and professionals can agree on common priorities

Mutual Agreement ↑42% absolute increase
(p<0.01)

Patient Engagement
Changes Priorities for Research

Registered Randomized Trials
- Psychosocial interventions, Education, Healthcare delivery: 59%
- Medical technologies: 23%
- Medications: 18%

Patient-clinicians research priorities (JLA)
- Psychosocial interventions, Education, Healthcare delivery: 59%
- Medical technologies: 23%
- Medications: 18%

Weber 2014
Patient Engagement increases recruitment in clinical trials

Effects of patient and public involvement (PPI) on enrolment in clinical trials
Meta-analysis of randomized studies

<table>
<thead>
<tr>
<th>Study</th>
<th>No of events/total PPI</th>
<th>No PPI</th>
<th>Total participants</th>
<th>Odds ratio (95% CI)</th>
<th>Odds ratio (95% CI)</th>
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<tr>
<td>Du 2008</td>
<td>16/63</td>
<td>10/63</td>
<td>126</td>
<td>1.80 (0.75 to 4.36)</td>
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<td>Hutchison 2007</td>
<td>62/86</td>
<td>66/87</td>
<td>173</td>
<td>0.82 (0.42 to 1.62)</td>
<td>0.92 (0.45 to 1.89)</td>
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<tr>
<td>Dear 2012</td>
<td>14/146</td>
<td>20/194</td>
<td>340</td>
<td>1.63 (1.00 to 2.67)</td>
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<tr>
<td>Man 2015</td>
<td>43/682</td>
<td>27/682</td>
<td>1364</td>
<td>1.11 (0.96 to 1.30)</td>
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<td>Guarino 2006</td>
<td>570/1412</td>
<td>522/1381</td>
<td>2793</td>
<td>1.02 (0.66 to 1.57)</td>
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<tr>
<td>Cockayne 2017a</td>
<td>63/2301</td>
<td>31/1149</td>
<td>3450</td>
<td>1.10 (0.71 to 1.69)</td>
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<tr>
<td>Cockayne 2017b</td>
<td>68/2301</td>
<td>31/1149</td>
<td>3450 Ford</td>
<td>1.38 (1.05 to 1.82)</td>
<td></td>
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<tr>
<td>2004</td>
<td>116/2949</td>
<td>95/3297</td>
<td>6246</td>
<td>1.16 (1.01 to 1.34)</td>
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<tr>
<td>Overall</td>
<td>952/9940</td>
<td>802/8002</td>
<td>17942</td>
<td></td>
<td>1.01 to 1.34</td>
</tr>
</tbody>
</table>

*Involvement of patients with lived experience of the condition significantly associated with improved recruitment (p=0.02)*

Crocker et al. BMJ 2018;363:k4738
Engaging with Patients in Trials

The Practice
Engaging with patients from the beginning

Impact of the COVID-19 pandemic on immunosuppressed graft/tissue/stem cell recipients and their relatives

We are still recruiting transplant recipients and their family members interested in contributing, as a volunteer research participant, to a study aimed at understanding the impact of the COVID-19 pandemic on immunosuppressed graft recipients and their relatives.

More specifically, this project aims to capture the modification of lifestyle habits, stress, anxiety levels and coping strategies of immunosuppressed graft recipients, their families and their relatives in the specific context of the containment associated with COVID-19 (objective 1). We also wish to study the impact of pet ownership on the stress experienced by this population and the benefits that pets can bring to organ recipients and their families (objective 2).

Please contact Stéphanie (stephanie.lariviere-beaudoin.chum@sss.gouv.qc.ca), the Project Manager, if you wish to learn more and join the study.

The research team.

Mélanie Dieudé (Ph.D.), Isabelle Doré (Ph.D.), Sylvain Bédard (Patient), Co-Investigators and Stéphanie Larivière, Project manager.
Are you ready to partner with patients?

1. **Willing to learn** from patients

2. Professional goals and **interpersonnel skills** compatible with partnership research (e.g. team player)

3. Ready to devote **time, energy and ressources** to develop and maintain collaboration

4. **Flexible in research goals** and potential that current project will be rejected/changed by patients

5. Willing to **share power and leadership**

Parry 2009
How do I start?

1. Clarify goals and roles

2. How ready are you?

3. Start simple…
Engaging with Patients in Trials

Key Messages
Engaging with Patients in Trials

1. Engaging upstream with patients can help doing the right research (questions, priorities and outcomes), and set the stage for doing research right (recruitment, implementation, adoption) when engaging downstream.

2. Productive partnerships require the right attitudes (team players, willingness to learn from each other), conditions (time & resources) and players (relevant lived experience).

3. Engagement is an art and a science: start simple and learn together as you go.
Thank you!

Together, I am Better

www.ceppp.ca
www.partnershipchair.ca